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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,273	04/13/2001	James R. LaDine	12800-003001	4611

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FISH & RICHARDSON PC
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,273

Applicant(s)

LADINE ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Amendment filed 06/07/2004 is acknowledged. Claims 3,4,19-21 are canceled. Claims 38--45 are added. Claims 1,2,5-18,22-45 are pending.

In regard to claims 29-37, drawn to a system for mass spectrometric analysis, applicant submits that it is obvious over the method of claims 1-18, 22-28 and therefore should not be restricted out. Examiner agrees, rejoins the claims and includes them into obviousness rejection of record.

Applicant's arguments have been fully considered and they are deemed to be persuasive-in-part. The references of Patterson and Wang are withdrawn from the rejection.

Claim Rejections - 35 USC § 103.

Claims 1,2,5-18,22-45 are rejected under 35 U.S.C. 103(a) as obvious over Demirev et al. (Analytical Chemistry (1997), 69(15), 2893-2900) or Chang et al (US 4507555).

The instant claims are drawn to method of analysis of plurality of proteins obtained from a biological system. The method comprises steps of separating multiple protein samples, analyzing them with parallel mass spectrometry and correlating mass spectrometry data as a function of time.

Parallel mass spectrometry is well known analytic technique developed in response to the need of analyzing multiple samples, biological samples, protein samples among them in particular. Thus, Demirev reference, cited in the initial rejection, explores feasibility of a "massively parallel" mass spectrometry and suggests that practical implementations of parallel mass spectrometry seem feasible for libraries containing from several hundreds to several thousand individual components, or for monitoring the diversity of up to a thousand reaction products at each subsequent step along the combinatorial synthetic pathway, and allow to examine various statistical parameters of the libraries that may be of practical importance in optimizing the synthetic pathway. See p. 2900, last two paragraphs.

Chang describes parallel mass spectrometer using example of analyzing signal from a single chromatography column, but acknowledges that the demonstrated system for parallel mass spectrometry system serves many variations, for example analysis of plurality of components among a complicated mixture. See col. 15, lines 7-12 and col. 5, lines 30-34

Therefore, it would be *prima facie* obvious to one skilled in the art at the time the invention is made to apply parallel mass spectrometry to any problem requiring simultaneous measurement of plurality of biological samples, such as, for example, measurement of plurality of protein samples. Further, it would be obvious to use parallel mass spectrometry to analyze plurality of protein samples to

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characterize response of biological system to a stimulus, which is a routine application of this analytical tool in biochemical analysis.

If there are any differences between the dependent claims Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach all particular combinations of limitations of the method as claimed, selection of optimal parameters would be conventional and within the skill of the art of analytical biochemistry.

Response to arguments

Applicant argues that the references do not teach multiple samples taken at multiple times. However, Demirev reference suggest exactly that, i.e., parallel measuring of thousands of compounds at various times. Chang, even though describing example of use of parallel mass spectrometry using signal from a single chromatography column, acknowledges that the demonstrated system for parallel mass spectrometry system serves many variations, for example analysis of plurality of components among a complicated mixture.

Examiner maintains that it would be obvious to apply parallel mass spectrometry to any problem requiring simultaneous measurement of plurality of biological samples, such as, for example, measurement of plurality of proteins from a quiescent or stimulated sample. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge

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generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. Further, the rationale to support a rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle. "In considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom". In re Prada , 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

September 10, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written below the printed name and title.